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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------------|
| 09/882,363 | 06/15/2001 | Eugene J. Alexander | 3104/105 | 6739 |
| 2101 7590 06/15/2007 BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618 | | | EXAMINER FOREMAN, JONATHAN M | |
| | | | ART UNIT 3736 | PAPER NUMBER |
| | | | MAIL DATE 06/15/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/882,363 | ALEXANDER ET AL. | |
| | Examiner | Art Unit | |
| | Jonathan ML Foreman | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007 and 06 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/6//06 has been entered.

Election/Restrictions

2. Applicant's election without traverse of Invention III in the reply filed on 3/29/07 is acknowledged.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 69 and 73 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. **11/410515**.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 69 and 73 of the present application is broader than claim 1 of Application No. **11/410515**.

As such, any reference meeting the limitations found in claim 1 of Application No. **11/410515** would necessarily meet the limitations of claims 69 and 73. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 74 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 74 and 75 recites the limitation "the at least one axis" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 69, 70 and 76 are rejected under 35 U.S.C. 102(a) as being anticipated by Eckstein et al. (1998 AJR 170; 593 – 596).

In regard to claims 69, 70 and 76, Eckstein et al. disclose obtaining an electronic image of a joint, wherein the image includes both normal and diseased cartilage tissue; electronically evaluating the image to obtain information including at least one of volume, area, thickness, shape, curvature geometry, biochemical contents, signal intensity and relaxation time of the normal and/or diseased tissue; and determining biomechanical data associated with the joint (Page 597, Col. 1). The biomechanical data includes static loading alignment in that the data is determined during a static loading position. The data is displayed (Page 594, “Digital Image Processing”).

10. Claims 69, 70, 71 and 76 are rejected under 35 U.S.C. 102(a) as being anticipated by Kshirsager et al. (Investigative Radiology, vol. 33, no. 5).

In regard to claims 69, 70, 71 and 76, Kshirsager et al. disclose obtaining an electronic image of a joint, wherein the image includes both normal and diseased cartilage tissue; electronically evaluating the image to obtain information including at least one of volume, area, thickness, shape, curvature geometry, biochemical contents, signal intensity and relaxation time of the normal and/or

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diseased tissue; and determining biomechanical data associated with the joint (Page 290, "Image Processing"). The biomechanical data includes static loading alignment in that the data is determined during a static loading position. Kshirsager et al. teach determining biomechanical data during joint motion (Page 298, Col. 1). The data is displayed.

11. Claims 69, 70 and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,560,476 to Pelletier et al.

In regard to claims 69, 70 and 76, Pelletier et al. disclose obtaining an electronic image of a joint, wherein the image includes both normal and diseased cartilage tissue; electronically evaluating the image to obtain information including at least one of volume, area, thickness, shape, curvature geometry, biochemical contents, signal intensity and relaxation time of the normal and/or diseased tissue; and determining biomechanical data associated with the joint (Col. 9, lines 48 – 51; Col. 12, lines 46 – 56). The biomechanical data includes static loading alignment in that the data is determined during a static loading position. The data is displayed.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kshirsager et al. in view of U.S. Patent No. 6,203,546 to MacMahon.

In regard to claims 77 and 78, Kshirsager et al. disclose the data being derived from a degenerative knee by an MRI but fail to disclose using the data to provide a therapy in the form of

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shaping an implant. However, MacMahon teach therapy for a degenerative joint in the form of shaping an implant using data derived from an MRI (Col. 5, lines 33 – 45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Kshirsager et al. to include providing a therapy in the form of shaping an implant as taught by MacMahon in order to provide the patient with a custom made implant to fit precisely within the joint.

14. Claims 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kshirsager et al.

Kshirsager et al. teach determining data during joint motion, but fail to disclose the joint motion being during a patient's gait. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Kshirsager et al. to determine data during a gait cycle of a patient in order to analyze the patient during a typical unconstrained movement.

Allowable Subject Matter

15. Claims 74 and 75 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

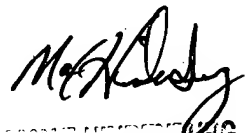
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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